



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 050972 0050 Rev. 02

Manufacturer:

Contec Medical Systems Co., Ltd.

No.112 Qinhuang West Street
Economic & Technical Development Zone
066004 Qinhuangdao, Hebei Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

**Shanghai International Holding Corp. GmbH
(Europe)**

Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

**Patient Monitor, Fetal Monitor, B-Ultrasound
Diagnostic System, Pulse Oximeter,
Electrocardiograph, Pocket Fetal Doppler,
Visual Electronic Stethoscope, Multi-
functional Visual Stethoscope, Dynamic
ECG Systems, Digital Brain Electric Activity
Mapping, Infusion Pump, Spirometer,
Ambulatory Blood Pressure Monitor,
Electronic Sphygmomanometer, EMG/EP
System, Portable ECG Monitor,
Temperature Probe, Pulse Oximeter Probe,
Tele Pulse Oximeter, Tele Breather, Multi-
parameter Vital Signs Monitor, Sleep apnea
screen meter, Oxygen concentrator, ECG
Workstation, Wearable Monitor.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

BJ1990207

Valid from:

2019-07-23

Valid until:

2024-05-26

Date,

2019-06-04

Stefan Preiß

Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zfg.de
 ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 050972 0050 Rev. 02

Facility(ies):

Contec Medical Systems Co., Ltd.
 No.112 Qinhuang West Street, Economic& Technical
 Development Zone, 066004 Qinhuangdao, Hebei Province,
 PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT